

## Certificate of Analysis

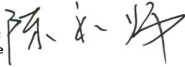
Number: FAPON-FR-T0-017

Edition: B.2

Product overview			
<b>Product Name</b>	Anti-CEA monoclonal antibody	<b>Catalog Number</b>	BECCEAS101
<b>Date of Manufacture</b>	Specific date	<b>Lot Number</b>	Specific lot number
<b>Immunogen</b>	N/A		
<b>Species</b>	Mouse	<b>Expressed Host</b>	N/A
<b>Tag</b>	N/A	<b>Clone number</b>	N/A
<b>Isotype</b>	IgG1	<b>Molecular weight</b>	150kDa
<b>Product buffer solution</b>	10mM PB+150mM NaCl+0.1% ProClin300,pH7.4	<b>Preservative</b>	ProClin300
<b>Storage Conditions</b>	-20±5°C, Avoid multiple freeze/thaw cycles	<b>Date of Expiration</b>	Shelf life:36 months
<b>Applications</b>	Capture	<b>Platforms tested</b>	N/A
Parameters tested on each lot			
<b>Product appearance</b>	Liquid		
<b>Conc.determined by</b>	N/A	<b>Concentration /Recommended titer</b>	Specific Concentration
<b>Purification</b>	N/A	<b>Purity</b>	≥90%
Performance:			
Items	Passing criteria		Qualified or not
<b>Immunoreactivity</b>	At the same working concentration, the deviation of the activity in the test group from the control group is within ± 10%.		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>Clinical specificity</b>	1. Internal negative control samples did not show any positivity during testing. 2. The slope was within range of 0.75-1.2 and R <sup>2</sup> is not less than 0.85, when the results of the test group and in the 80 positive samples were compared.		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>Product stability</b>	When accelerated stability testing at 37°C was performed, No change in specificity testing of the internal controls samples was observed and the change in activity was not higher than 20%.		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

Miscellaneous	N/A	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Remark	N/A		
Conclusion	Pass <input checked="" type="checkbox"/> Fail <input type="checkbox"/>		
Quality signature	N/A	Quality inspection date	N/A

管理者代表:  
Management representative



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